

have been measured with knowledge and satisfaction questionnaires, but have not been assessed within a choice-based methodology. The key function of a decision aid is to provide information for a patient to make an informed decision and the displaced activity within the health care system (the opportunity cost) would be physician consultation time. We propose a stated preference consultation time trade-off (CTTO) in which a proportion of a hypothetical 10-minute physician consultation is traded for use of the decision aid by a patient with prior experience of the aid. Conceptually, a patient is trading a substitute source of health care information to maximise their utility of the consultation experience. The CTTO may be reported in consultation minutes or converted to a monetary value using the local cost of physician time. These values can be used, alongside the cost of the decision aid, for economic evaluation. The CTTO is currently being evaluated within a clinical trial of a cataract decision support tool.

#### PRM220

##### DIRECT-TO-PATIENT STUDY DESIGNS FOR PHARMACOVIGILANCE

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Post-marketing non-interventional safety studies typically enroll patients at sites where patients receive care. During patient follow-up the occurrence of safety events of interest is recorded by site personnel based on information obtained from the patient during standard-of-care visits. Although this is the traditional approach for assessing the occurrence of safety events in the post marketing setting, it has several practical shortcomings, including: high cost associated with site start up, management, and data collection; infrequent or irregular standard-of-care visits; patients switching health care providers; transient nature of some safety events; treatment at non-study sites, and the lack of care-seeking for the safety events. A design alternative that overcomes several of these shortcomings includes direct-to-patient contact and follow-up. In this approach, enrolled patients are regularly contacted via phone during follow-up and interviewed regarding the occurrence of safety events or potential signs and symptoms associated with the safety events. If either is reported by the patient, trained personnel follow up with the patient's treating physician for further evaluation through phone interview and/or written confirmation of the safety event. We will present three examples of studies that make use of this direct-to-patient approach to capturing safety data. These studies comprise large multi-national and national studies with sample sizes ranging between 2000 to over 10,000 patients. In one study, the safety events include thromboembolic and bleeding events in patients discharged from hospitalization for acute coronary syndrome. In two others, safety events comprise anaphylaxis, encephalitis, Bell's palsy, neuritis, etc. associated with influenza vaccines. For each study, we will present specific design characteristics; procedures for patient contact, follow-up, and interviews; and procedures for confirming the occurrence of safety events. Strengths and weaknesses of the direct-to-patient approach will be discussed and recommendations regarding appropriate indications and safety events best suited to this novel methodology will be presented.

#### PRM221

##### MPR AND PDC: IMPLICATIONS FOR INTERPRETATION OF ADHERENCE RESEARCH RESULTS

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**OBJECTIVES:** To compare and contrast the Medication Possession Ratio (MPR) and Proportion of Days Covered (PDC) measures of adherence and explore the implications of measure choice and specific definition on study results. **METHODS:** Two adherence measures, MPR and PDC, were selected for comparison because of their prominence in the claims database research literature. To highlight the effect of measure selection, examples demonstrating contrasting results for MPR and PDC are presented. Furthermore, the impact of numerator and denominator specification within each of those measures is examined and illustrated with examples. Implications for assessing and interpreting published research studies are presented. **RESULTS:** Although MPR and PDC have been operationally defined in similar ways in the literature, there are differences that could yield distinct results. The basic structure of these measures is a ratio with a proxy for the number of compliant days in the numerator and the number of days in a measurement period in the denominator. MPR is based on the sum of dispensed 'days supply' over a period, whereas PDC is based on evaluation of available supply for each individual day in the period. A demonstration is provided on how research design choices of MPR or PDC and specification of numerator and denominator can result in different findings for a given research question. **CONCLUSIONS:** Despite the similar structure of MPR and PDC metrics, study design choices can affect study results considerably. Selection of an adherence measure must be tailored to the therapeutic area, relevant medications, and research objectives. Researchers should be transparent in the specification of measures used and readers need to understand the implication of these research design decisions.

#### PRM222

##### EVALUATING THE COST OF OPIOID DEPENDENCE TREATMENT MODELS IN EUROPE

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Opioid dependence incurs significant harm and associated economic costs worldwide. Whilst investment in medication-assisted treatment interventions cost-effectively reduces these harms, models of care for opioid dependence

vary substantially between countries. Quantification of opioid-dependence treatment costs could help to optimise health policy decision-making regarding treatment provision. A health economic (HE) model was developed to calculate the costs associated with different treatment models of care in use across Europe allowing for comparison of different treatment systems. Total costs incurred, on a per-patient and national level, were calculated. A literature review was undertaken in order to find all relevant evidence on the treatment of opioid dependence. The HE model assesses direct costs (including medications, supervision and dispensing, staff costs, testing costs, other health care costs and miscellaneous costs) associated with the model of treatment in place in each country, according to national guidelines, and allows for comparison of the costs associated with different medication options. Local cost data were sourced by health economics groups in each of the relevant countries, and were drawn from publicly available databases and published literature where possible. Expert opinion was used to fill in any remaining data gaps. Seven countries were included in the analysis with the initial focus being Belgium, France, Germany, Italy, Portugal, Spain and UK. The primary output of the HE model, which will be presented, is the total per-patient cost of providing treatment for opioid dependence in each country. The HE model also provides the total cost of each treatment model in each country. Outputs are being validated against publicly available statistics on the total number of patients treated and the total cost to treat them, in each country. This HE model provides a tool to support discussions on and implementation of cost-effective models of care for opioid dependence around Europe.

#### PRM223

##### IMPLEMENTATION OF PATIENT-REPORTED OUTCOMES ASSESSMENT IN A POST MARKETING SAFETY SURVEILLANCE: PARALLELS IN JAPAN AND GLOBAL PLANNING

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The importance of incorporating patient-reported outcomes (PRO) assessment into the practice of medicine is well recognized. Measurement of PRO in real-world clinical practice, however, is not commonly performed because of limited time spent with patients due to the busy schedules of clinicians, whose primary focus is to achieve a symptomatic cure. A post marketing safety surveillance (PMS) is one of a few opportunities to obtain non-interventional, prospective, real-world data about PRO, since PMS is a must due to regulatory requirements in many countries. Indeed, cross-continent planning and collaboration will be required to understand similarities and differences as PMS studies become a standard practice for multi-national research. Whereas PRO results are useful to evaluate patient-relevant effectiveness of the drug, the implementation of a PRO survey in PMS in different countries requires careful preparation, such as: facilitate multidisciplinary team communications for proper design of a PRO survey and selection of a validated survey questionnaire for all participating countries; strategize the recruitment of clinicians and patients; develop training materials for patient recruitment; handle adverse-event-like symptom questions in a questionnaire for adverse drug reaction reporting; develop the report format of PRO survey results to regulatory authorities; and develop a communication plan of PRO assessment results to stakeholders, such as physicians and patient organizations. We will discuss above issues associated with a PRO survey as a part of PMS from both Pharmacovigilance and Outcomes Research points of view based on our experience in Japan. A comparison will also be made about study planning with a PRO component between Japan and global PMS (such as the Post-Authorization Surveillance required by the European Medicines Agency), to highlight important lessons and implications for PRO researchers and practitioners to enhance the usage of PMS as a valuable opportunity to obtain real-world PRO assessments.

#### PRM224

##### ELECTRONIC PATIENT REPORTED OUTCOMES (ePRO): THE BEST DEFENSE IN PREVENTING MISSING PRO DATA

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This session will illustrate how ePRO is a powerful approach for preventing missing data; explain how ePRO is more effective as compared to paper; and demonstrate how ePRO techniques can be implemented to prevent missing data. ePRO use can be an effective solution for preventing missing data as compared to paper data collection. Missing data is common in PROs and can result in significant problems for data analysis. While using a robust statistical plan for handling missing data is beneficial, studies still can suffer with high levels of missing data. One major contributing factor is the collection method. Many PROs are still administered in a traditional paper format which can result in high levels of missing data. This presentation will illustrate how ePRO can prevent missing data through providing examples of various ePRO techniques that can be implemented. Primary ePRO techniques to minimize missing data include: hard edit check to eliminate patients from skipping items or pages; reminders with real time technology to remind patients to complete their PROs; alerts to study staff of patient non-compliance; programmed logic to reduce erroneous entries and contradicting responses; time stamped data entry to ensure assessments are completed within the given window; and storage of directly entered data with back-up can ensure data is not lost. ePRO can prevent missing data, improve patient compliance and result overall in high quality data. ePRO eliminates many of the issues associated with data loss in traditional paper-based PRO systems. Future PRO development efforts should focus on creating more electronic versions of PRO instruments. Wider availability of ePRO instruments across therapeutic areas would ultimately result in high quality data and reduced missing data.